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|--|-------------|----------------------|------------------------|------------------|
| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.    | CONFIRMATION NO. |
| 10/723,323   | 11/26/2003  | Enrico Alessi        | 64659-00003USPX        | 9467             |
| 23932 7590 03/21/2007<br>JENKENS & GILCHRIST, PC<br>1445 ROSS AVENUE<br>SUITE 3200<br>DALLAS, TX 75202 |             |                      | EXAMINER<br>LIN, JERRY |                  |
|  |             |                      | ART UNIT               | PAPER NUMBER     |
|  |             |                      | 1631                   |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE   |             | MAIL DATE            | DELIVERY MODE          |                  |
| 3 MONTHS   |             | 03/21/2007           | PAPER                  |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/723,323 | <b>Applicant(s)</b><br>ALESSI ET AL. |  |
|                              | <b>Examiner</b><br>Jerry Lin         | <b>Art Unit</b><br>1631              |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 13, and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicants' arguments, filed December 18, 2006, have been fully considered and they are deemed to be persuasive in-part. The following rejections and/or objections are either reiterated or newly applied as necessitated by amendment. They constitute the complete set presently being applied to the instant application.

### ***Status of the Claims***

Claims 1-8, 13, and 14 are under examination.

Claims 9-12 are withdrawn as being drawn to an unelected invention.

### ***Claim Rejections - 35 USC § 101***

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claims are drawn to a mathematical algorithm for clustering gene datasets that includes clustering data, pairing datasets, calculating parameters of paired datasets, determining a value based on the parameters, and identifying pairs with values greater than a threshold.

In regards to claims 1-8, the instant claims are drawn to a mathematical algorithm. A mathematical algorithm is non-statutory unless the claims include a step of physical transformation, or if the claims include a useful, tangible and concrete result. It

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is important to note, that the claims themselves must include a physical transformation step or an useful, tangible and concrete result in order for the claimed invention to be statutory. It is not sufficient that a physical transformation step or a useful, tangible, and concrete result be asserted in the specification for the claims to be statutory. In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims include a useful, tangible, and concrete result.

In determining if the instant claims are useful, tangible, and concrete, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, substantial, and credible. For a claim to be "tangible," the claim must set forth a practical application of the invention that produces a real-world result. For a claim to be "concrete," the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete result in the claim itself, and the claim must be limited only to statutory embodiments. Thus, if the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

The instant claims do not include any tangible result. A tangible requirement requires that the claim must set forth a practical application of the mathematical algorithm to produce a real-world result. However, the instant claims do not arrive a real world result. Rather, the instant claims end with a final process, the process of identifying. This does not necessarily lead to a result. Since the instant claims do not necessarily lead to a result, the instant claims do not include any tangible result.

Response to Arguments

4. The Applicants have responded to this rejection by amending claim 1 to include the limitation of "identifying the groups of genes . . . . ." However, this amendment does not require that the instant claims have a tangible result. The final step in the claims still is a process that may or may not lead to a result. Since the instant claims do not necessarily lead to a result, the instant claim cannot have a tangible result. The Examiner suggests that the Applicants include language that includes a readily accessible result, such as an output to a display, a printout, or saving the results to a readily accessible computer medium.

This rejection is maintained from the previous office action.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 3-7, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shamir et al. (US 2003/0224344) in view of Dougherty et al. (Journal of Computation Biology (January 2002) Volume 9, Number 1, pages 105-126) further in view of Tolley (US 2004/0128080).

The instant claims are drawn to a method of clustering wherein a dataset is clustered in to smaller datasets, the smaller datasets are paired, characteristic parameters of the pairs are calculated, a value is generated as a function of the parameters, and pairs with values greater than a threshold are identified as "Gene Networks" and pairs with values lower than a threshold are discarded.

Regarding claims 1 and 13, Shamir et al. teach a method of clustering wherein a dataset is clustered (data is generated in relation to time or environmental conditions)(page 1, paragraph 0004-0008; page 2, paragraph 0011-0021); where groups of genes satisfy a clustering criterion (page 2, paragraph 0011-0021); establishing pairs of sub-tables (clusters) (page 2, paragraph 0015-0017); calculating the parameters of the data in each pair combination (page 2, paragraph 0015-0017); and identifying pair combinations whose values is greater than a threshold as "Gene Networks" (genes involved in the same cellular process) and discarding combination (not clustering together) genes whose values are smaller than a threshold (page 2,

paragraph 0015-0017). Shamir et al. also teach outputting the results (page 8, paragraph 0102).

However, Shamir et al. do not disclose using a decision algorithm based on soft computing or wherein the datasets are presented in tables.

Regarding claims 1 and 13, Tolley teaches using clustering algorithms on datasets that are presented in tables (page 7, paragraph 0059-0062).

Regarding claims 1, 3 and 13, Dougherty teaches that data may be clustered using a variety of soft computing techniques including fuzzy logic (abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method of Shamir et al., Dougherty et al. and Tolley to incorporate the benefits of fuzzy logic in the method of Shamir et al. Shamir et al. states that their goal is to create a more accurate clustering method (page 2, paragraph 0021). Shamir et al. attempt to create a more accurate clustering method by introducing more weights to a clustering means (page 2, paragraph 0021). Dougherty et al. is also concerned with improving the accuracy of clustering algorithms (abstract). In order to determine the best clustering algorithms, Dougherty et al. compares several known techniques. They find that Fuzzy logic as one of the means that has more accuracy than other means (page 118-page 120, top). Thus, one of ordinary skill in the art seeking to improve the accuracy of clustering algorithms would be motivated to combine the methods of Dougherty et al. and Shamir et al., since each method improves different components of a clustering algorithm. Furthermore, Tolley teaches that database are typically organized in tables (page 7, paragraph 0057). Thus one of ordinary skill in the

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art would expect to perform the method of Dougherty et al. and Shamir et al. on a database organized in tables.

Regarding claim 4, Shamir et al. teach wherein the parameter is tied to gene expression levels (page 1, paragraph 0006).

Regarding claim 5, Shamir et al. teach wherein the parameter is a correlation coefficient (page 5, paragraph 0054; page 8, paragraph 0095).

Regarding claim 6, Shamir et al. teach wherein low degree vertices (low number of genes) are eliminated (page 2, paragraph 0018-0019).

Regarding claim 7, Dougherty et al. disclose using SOM or K-means clustering (page 1118).

Regarding claim 14, Dougherty et al. teach training the fuzzy logic not using any on-line capabilities (page 124).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method of Shamir et al., Dougherty et al. and Tolley to incorporate the benefits of fuzzy logic in the method of Shamir et al. As stated above, one of ordinary skill in the art would be motivated to incorporate fuzzy logic with Shamir et al.'s method. Thus one of ordinary skill in the art would combine Shamir et al. with the specific techniques taught by Dougherty et al. such as fuzzy logic not using any online capabilities or SOM or K-means clustering.



Response to Arguments

7. The Applicants first point out that there has been no art rejection applied to instant claim 8. The Examiner acknowledges this, however, he cannot indicate that claim 8 is allowable since it remains rejected under another statute (35 USC §101) from the previous office action, and would remain rejected under 35 USC §101 even if written in an independent form.

The Applicants first state that Shamir et al. does not teach using the operation based on table/sub-table analysis. The Examiner acknowledges this in the previous office action. However, the Examiner is stating that Shamir et al. teaches the operations as in the claims and it would be obvious to present them in tabular format as taught by Tolley. The Applicants did not reply to the combination of Shamir et al. and Tolley.

The Applicant then states that Shamir et al. does not teach the recited characteristic value. The Examiner disagrees. As was cited in the previous office action on page 2, paragraphs 0015-0017, Shamir et al. calculate the parameters which take the form of values. Specifically, Shamir et al. teach "If the subgraph satisfies a stopping criterion, then the subgraph is designated as a cluster." It is this criterion that is a characteristic value.

Finally the Applicant then state that Shamir et al. does not teach discarding pair combinations of groups of genes where the characteristic value is smaller than the threshold. The Examiner disagrees. Shamir et al. states "The input data is represented as an unweighted similarity graph in which there is an edge between two vertices if and

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only if the similarity between their corresponding elements exceeds a predefined threshold.” Shamir et al. is stating that the genes are clustered as being members of a network of genes only when the threshold is exceeded.

Regarding claim 2, the Applicants state that Shamir et al. does not teach logic filtering criteria. The Examiner agrees, and the rejection under Shamir et al. is withdrawn as it applies to claim 2.

This rejection is maintained from the previous office action.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

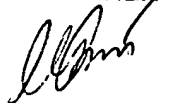
**Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00-6:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MICHAEL BORIN, PH.D  
PRIMARY EXAMINER



JL